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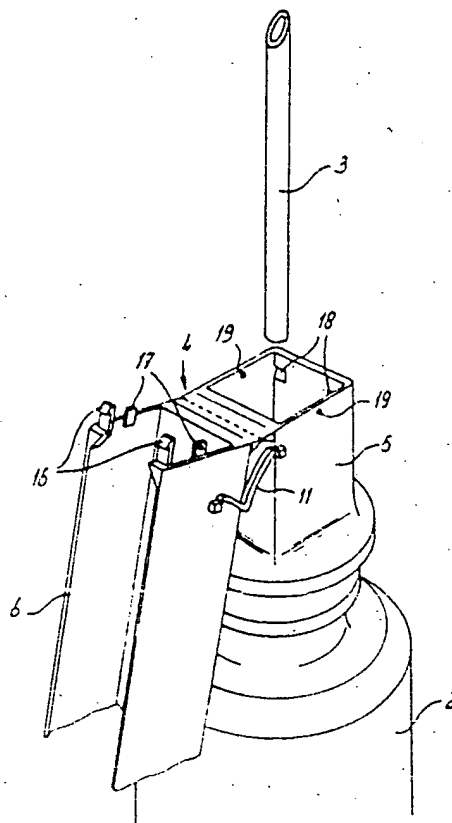
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## Published

*With international search report.**Before the expiration of the time limit for amending the  
claims and to be republished in the event of the receipt of  
amendments.*(54) Title: PROTECTIVE DEVICE FOR A PIERCING OR CUTTING OBJECT FOR MEDICAL PURPOSES, SUCH AS A  
HYPODERMIC NEEDLE

## (57) Abstract

Provision is made for a protective device (4) for a piercing or cutting object for medical purposes, such as a hypodermic needle (3), comprising a base part (5) to which the piercing or cutting object can be attached, and a protective element (6) which is hingedly connected by means of a hinge line (9) to the base part (5), and can be pivoted into a first position, in which said protective device at least partially encloses the piercing or cutting object, and into a second position, in which the piercing or cutting object is released and its use is essentially not impeded by the protective device. According to the invention, at the side of the protective device (4) where the hinge line (9) is situated, the protective element (6) is further connected to the base part (5) by means of at least one resiliently deformable member (11), of which the fastening point to the base part (5) and the protective element (6) respectively is situated at a distance from the hinge pin of the hinge line, in such a way that in the first position of the protective element (6) the direct connecting line between said respective points lies at the side of the hinge line (9) facing the piercing or cutting object, and in the second position of the protective element (6) lies at the opposite side of the hinge line (9).



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Title: Protective device for a piercing or cutting object for medical purposes, such as a hypodermic needle.

The present invention relates to a protective device for a piercing or cutting object for medical purposes, such as a hypodermic  
5 needle, comprising a base part to which the piercing or cutting object can be attached, and an essentially sleeve-shaped protective element which is U-shaped in cross-section and is hingedly connected by means of a hinge line to the base part, and can be pivoted into a first position, in which said protective device at least partially encloses the piercing  
10 or cutting object, and into a second position, in which the piercing or cutting object is released and its use is essentially not impeded by the protective device.

Such a protective device is used to prevent injury, incurring the risk of infection, before or after use of the piercing or cutting  
15 object. In addition, such a protective device can prevent the piercing or cutting object from being used for a second time, which again prevents cross-infection between patients. Many different protective devices of this type have therefore been developed. For example International Application WO 90/01348 and US Patent Specification 4,976,699 disclose a  
20 protective device in which the protective element is hingedly connected to the base part. The disadvantage of these known protective devices is that they have to be operated with both hands to move the protective element into the first and the second position. In addition, the protective element can be pivoted through only 90°. Besides, such known  
25 protective devices require a relatively large quantity of material, inter alia because of the construction details which have to be provided, such as handles and locking provisions for moving the protective element into and holding it in the first and second position.

The object of the present invention is to provide a protective  
30 device of the type mentioned in the preamble which is simple in design and is easy to manufacture by, for example, injection moulding, is practical in use, mainly through the fact that returning the protective element to the first position can be carried out simply and efficiently with one finger in a relatively short movement, for which relatively  
35 little material is required, and of which the protective element is easy to move into and hold in the first or second position.

For this purpose, the protective device according to the present invention is characterised in that, at the side of the protective

device where the hinge line is situated, the protective element is further connected to the base part by means of at least one resiliently deformable member, of which the fastening point to the base part and the protective element respectively is situated at a distance from the hinge pin of the hinge line, in such a way that in the first position of the protective element the direct connecting line between said respective points lies at the side of the hinge line facing the piercing or cutting object, and in the second position of the protective element lies at the opposite side of the hinge line.

10 This specific embodiment of the hinge connection between the base part and the protective element, with the presence of a resiliently deformable member means, that a protective device which operates efficiently can be provided by a relatively simple design requiring little material. The base part and the protective element in this case  
15 can be injection moulded integrally, which makes mass production possible. It is also possible with the invention to fit all provisions for efficient functioning of the protective device on one side thereof. This means that the user is impeded as little as possible by the protective device during use of the piercing or cutting object.

20 Made of, for example, plastic, the resiliently deformable member can advantageously consist of two legs which are directed essentially at right angles to each other, and which are rigidly connected to each other. All this will become clearer from the description of the figures, and this design produces a resiliently  
25 deformable member with relatively long spring travel.

In order to ensure that the protective element can be moved efficiently and reliably into and held in the first or the second position, it is preferable for the hinge line to be placed radially outside the protective element and the base part. For this purpose,  
30 protective element and base part can be provided with one or more radial projections which are connected to the hinge line. These projections are formed by solid ridges. This makes the design of the injection mould simple, while a stable, reliable hinge is produced.

In order to facilitate the production by injection moulding, it  
35 is preferable that a resiliently deformable member should be situated on either side of the hinge line, in a manner such as that which is explained in greater detail, for example, in the description of the figures.

It is also preferably possible for the protective element and

the base part to be anchored to each other in the first position of the protective element, for example in order to prevent an inadvertent subsequent use of the piercing or cutting object. This anchoring can be, for example, by means of snap elements which are activated as soon as the protective element is moved out of the first position for the first time. This anchoring can also be achieved if first and second snap elements are present and are positioned in such a way relative to the respective snap chambers that, when the first or second snap elements are snapped into the respective snap chambers, the second or first snap elements lie outside the respective snap chamber. This will be explained in greater detail in the description of the figures. In order to prevent repeated use, it is also possible to provide the protective element, at its end facing away from the base part, with one or more snap elements which can snap into snap chambers in the protective element when the lip-shaped element is pivoted into a position in which it at least partially covers an opening which is provided in the protective element to allow through the piercing or cutting object. This lip can also be used for pivoting the protective element out of the first position into the second position. In order to fix the protective element with the base rotatable on the piercing or cutting object, it is preferable to equip said base with a hook element, which can grip behind a peripheral edge.

The invention will be explained in greater detail below with reference to a non-limiting embodiment shown in the appended figures, in which:

Fig. 1 shows a perspective view of a part of the protective device according to the present invention, fitted on an only partially shown hypodermic syringe, with the protective element in the first position;

Fig. 2 shows a side view of the assembly shown in Fig. 1;

Fig. 3 shows a view corresponding to Fig. 2, with the protective element in an intermediate position between the first and the second position;

Fig. 4 shows a view corresponding to Fig. 2, with the protective element in the second position;

Fig. 5 shows a perspective view of a part of a second embodiment of the protective device according to the present invention, fitted on an only partially shown hypodermic syringe, with the protective element in the second position;

Figs. 6 and 7 show a side view of a detail of the protective

device of Fig. 5, in partial cross-section near the hinge;

Fig. 8 shows a side view of a third embodiment of the protective device according to the present invention, fitted on an only partially shown hypodermic syringe.

5 With reference to the figures, a hypodermic syringe 1 is shown, having a squeeze-out holder 2 for holding medical liquids, and a hollow needle 3 which is connected to the holder 2.

The protective device 4 according to the present invention is also placed on the holder 2. Said device comprises a base part 5 which is  
10 connected to the needle base 14, and a protective element 6 hingedly connected to the base part 5. This protective element 6 encloses the hollow needle 3 over its full height, and is shown only partially in Fig. 1. The base part 5 and the protective element 6 are each provided with a radially projecting ridge 7 and 8 respectively, which are  
15 interconnected by means of the hinge line 9. The hinge line 9 thus lies radially outside the base part 5 and the protective element 6.

Resiliently deformable members 11 are provided on either side of the hinge line 9. In the released position, said members each comprise two legs situated at right angles to each other and connected to each other,  
20 one free end of which is connected to the base part 5, while the other free end is connected to the protective element 6 at a distance from the hinge pin of the hinge line 9. The fixing point of the members 11 to the base part 5 and the protective element 6 respectively is in this case selected in such a way that, in the first position of the protective  
25 element 6, shown in Fig. 2, the direct connecting line between said fixing points lies at the side of the hinge line 9 facing the protective device 4, and in the second position of the protective element 6, shown in Fig. 4, lies at the side of the hinge line 9 facing away from the protective device 4. Fig. 3 shows the position of the protective element  
30 6 in which the connecting line between the fixing points and the member 11 on protective element 6 and base part 5 respectively exactly intersects the hinge line 9. The member 11 is resiliently deformed in this case. In this position there is an unstable equilibrium for the protective element 6. If there is a slight movement of the protective  
35 element 6 in the direction of the arrow A, it will be moved through the resilient action of the member 11 into the position shown in Fig. 2; and, if there is a slight movement in the direction of the arrow B, the position shown in Fig. 4 will be reached. In the second position of the protective element 6, shown in Fig. 4, very little impeding effect is

encountered from the protective device 4 during the use of the hypodermic syringe 1. For the purpose of fulfilling their function, each member 11 is easily hingedly fixed by its free ends to projections of the base part 5 and the protective element 6. As Figs. 1 and 2 show, in the first position of the protective element 6 the leg of the member 11 running from the base part 5 to the protective element 6 is directed essentially parallel to the lengthwise direction of the needle 3. The protective element can consequently swing through almost 180° about the hinge 9.

A snap element 12 is situated on the base of the protective element 6, at the opposite side of the hinge line 9. Said element can be activated in the known way as soon as the protective element 6 is moved out of the first position, shown in Fig. 2, for the first time, so that after the protective element 6 is returned to the first position, said snap element 12 snaps into the snap chamber 13 in the base part 5, with the result that the protective element 6 cannot easily be moved out of its first position again.

As shown in Figs. 2 - 4, a hook element 32 also projects from the bottom side of the base part 5. This element grips behind a peripheral edge 33 on the base of the needle 3. The protective device 4 can consequently easily be connected to the needle base 14 as a separate part, and can be rotated about the needle base 14, so that the correct position of the protective element 6 relative to the bevelled point of the needle 3 can be selected as required. For the same purpose, the base part could also be provided with a peripheral groove, which runs through, for example, 180°, and in which a projection on the periphery of the base of the needle 3 is inserted, or vice versa.

Fig. 5 shows a hypodermic needle 3 with a moulded-on base 14, which is placed on holder 2 in the usual way (for the sake of clarity, only the top part of the needle 3 is shown here). The base part 5 is in this case designed in such a way that it can easily be placed on the base 14 of the needle 3, and can be glued on it. The protective element 6 is also provided with first snap elements 16 and second snap elements 17, which can snap into first snap chambers 18 and second snap chambers 19 respectively, which are cut out in the base part 5. As Figs. 6 and 7 show, the first and second snap elements 16, 17 are designed in such a way that in the position shown in Fig. 6 the snap elements 17 are snapped into the corresponding chambers 19, and the snap elements 16 are not snapped into the corresponding chambers 19, while the opposite is the case in Fig. 7. The snap elements 17 also provide a relatively light

locking force, which is relatively easy to break. The snap elements 16, on the other hand, provide a considerably greater locking force. The protective element 6 can thus be moved relatively easily out of the position shown in Fig. 6 into the position shown in Fig. 5. After use, the protective element 6 can then be pivoted back into the protecting position, as shown in Fig. 7, from which it is almost impossible to move it again. In order to prevent the protective element from being accidentally moved from the position shown in Fig. 6 into the position shown in Fig. 7 during transportation, a tear-off strip 20, as shown in Fig. 6, can be provided. After removal of said strip 20, the protective element 6 can be pivoted. This tear-off strip can be integral with the shut-off film (not shown) for shutting off the U-shaped section, for storage and the like. A spot-welded connection between protective element 6 and member 11 can also be used for this application.

Fig. 8 shows yet another solution for preventing repeated use of the needle 3. In this example, the base part 5 is integral with the needle base 14, which is placed in the usual way on the holder 2. A lip-shaped element 21 is provided at the free end of the protective element 6 with U-shaped cross-section. Said lip-shaped element 21 extends between the legs of the U-shaped protective element 6. Said element 21 is provided with snap elements 22 projecting on either side. The protective element is provided with corresponding snap chambers 23. In the position of the element 21 shown by dashed and dotted lines it can serve as a handle for pivoting the protective element 6. The element 21 can then easily be moved into the position shown by solid lines using, for example, the thumb. In that position, the space between the legs of the U-shaped element is covered, and the snap elements 22 are snapped into the chamber 23. In this way the needle 3 is completely enclosed, and the protective element can no longer be pivoted in such a way that the needle can be used. In that position the lip-shaped element 21 also presses the free end of the needle 3 resiliently to the side, so that the protective element is made virtually immovable.

Of course, the invention is not restricted to the example of an embodiment described above and shown in the figures. For example, it is possible to close off the open side of the U-shaped section of the protective element 6 with a tear-off strip in the manner known from PCT WO 88/00477, or to shut it off with an adhesive strip. The protective element 6 can also be provided with snap sections at the free ends of the legs of the U-shaped section, as also known from the last-mentioned

international application, so that after use with the protective element 6 in its first position the spring ends of said legs can be moved towards each other until the snap elements are in engagement with each other, with the result that the hollow needle 3 has been made reliably  
5 inaccessible. In order to facilitate the bringing together of the free ends of the U-shaped section, the body thereof can be provided with one or more weakening lines running over its height. The protective device shown can also be used for, for example, protecting a scalpel. For example, the legs of the U-shaped section of the protective element 6  
10 must then be extended. The resiliently deformable member 11 can also be designed differently, for example in the form of a (metal) coil spring or leaf spring. Moreover, the base part 5 can be integral with the needle 3 or its base 14. Embodiments combining features of the different designs shown here are also conceivable.

15         The invention thus provides a protective device with an advantageous and material-saving design, which can be produced by injection moulding, and the protective element 6 of which is easy to move into and hold in its first or second position, having little impeding effect in the second position, all this as described in greater detail in  
20 the appended claims.

## CLAIMS

1. Protective device for a piercing or cutting object for medical purposes, such as a hypodermic needle, comprising a base part to which the piercing or cutting object can be attached, and an essentially sleeve-shaped protective element which is U-shaped in cross-section and is hingedly connected by means of a hinge line to the base part, and can be pivoted into a first position, in which said protective device at least partially encloses the piercing or cutting object, and into a second position, in which the piercing or cutting object is released and its use is essentially not impeded by the protective device, characterised in that, at the side of the protective device (4) where the hinge line (9) is situated, the protective element (6) is further connected to the base part (5) by means of at least one resiliently deformable member (11), of which the fastening point to the base part and the protective element respectively is situated at a distance from the hinge pin of the hinge line, in such a way that in the first position of the protective element the direct connecting line between said respective points lies at the side of the hinge line facing the piercing or cutting object, and in the second position of the protective element lies at the opposite side of the hinge line.
2. Protective device according to Claim 1, in which in the released position thereof the resiliently deformable member (11) is essentially L-shaped, and the free ends of the member (11) are connected to the base part (5) and the protective element (6) respectively in such a way that they are easily swung.
3. Protective device according to Claim 2, in which the short leg of the member (11) is connected to the base part (5), in such a way that in the first position of the protective element (6) the member (11) essentially assumes the released form, with the long leg directed essentially parallel to the piercing or cutting object (3).
4. Protective device according to Claim 1, 2 or 3, in which the protective element (6) and the base part (5) are provided with one or more radial, essentially rigid projections (7, 8), which are connected by the free end to the hinge line (9).
5. Protective device according to one of the preceding claims, in which a resiliently deformable member (11) is situated on either side of the hinge line (9).
6. Protective device according to one of the preceding claims, in which the protective element (6), the base part (5) and the resiliently

deformable member (11) are integral.

7. Protective device according to one of the preceding claims, in which, at their ends facing each other, the protective element and the base part are provided with anchoring means for connecting the protective  
5 element and the base part to each other in such a way that in the interacting position of said anchoring means, the protective element is rigidly connected to the base part.

8. Protective device according to Claim 7, in which the anchoring means comprise at least one snap element (12) and a snap chamber (13) to  
10 be brought into anchoring interaction therewith.

9. Protective device according to Claim 7 or 8, in which first and second snap elements are present, which elements are positioned in such a way relative to the respective snap chambers that when the first or  
15 second snap elements are snapped into the respective snap chambers, the second or first snap elements lie outside the respective snap chamber.

10. Protective device according to one of the preceding claims, in which, at its end facing away from the base part, the protective element is provided with a hingedly fixed lip-shaped element (21), which is provided with one or more snap elements (22), which can snap into snap  
20 chambers (23) in the protective element (6) when the lip-shaped element is pivoted into a position in which it at least partially covers an opening which is provided in the protective element to allow through the cutting or piercing object.

11. Protective device according to one of the preceding claims, in  
25 which the base part (5) is provided with a hook element (32) which is capable of gripping behind a peripheral edge of the base (14) of the object (3).

12. Assembly of a piercing or cutting object for medical purposes, such as a hypodermic needle with a squeeze-out holder, having a  
30 protective device according to one of the preceding claims.

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fig-1

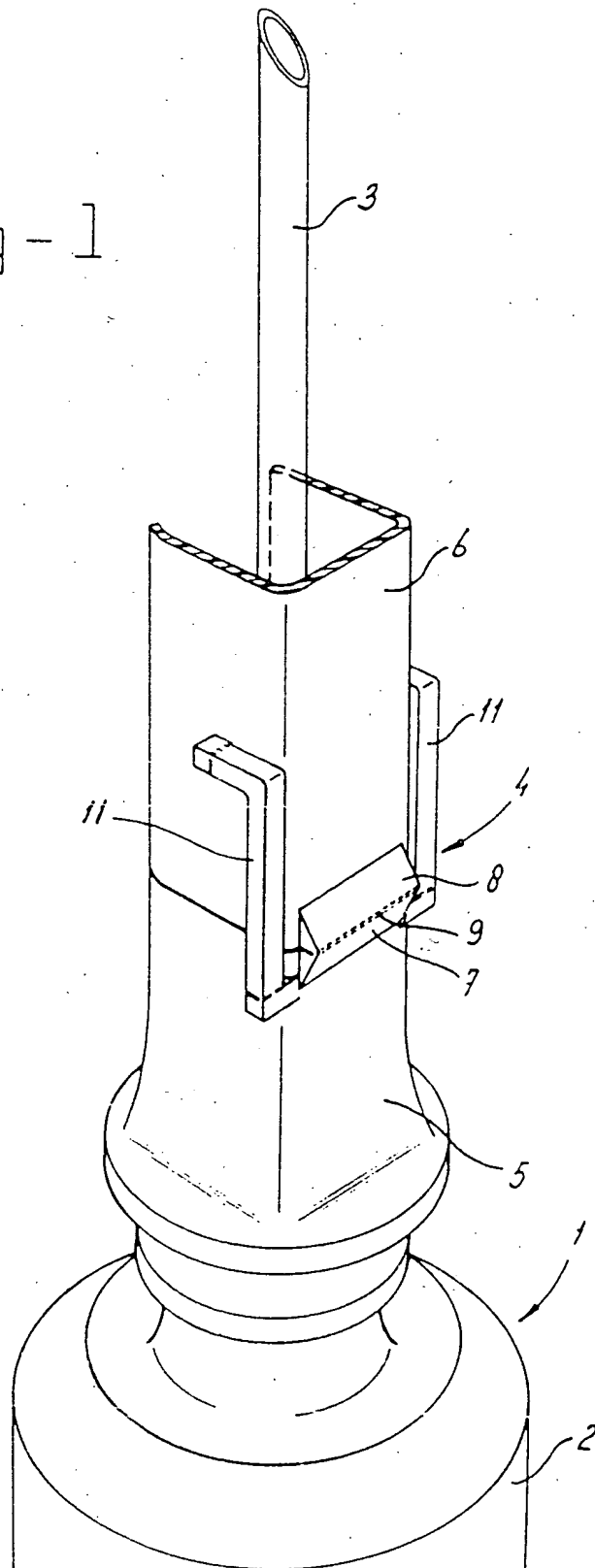


fig-2

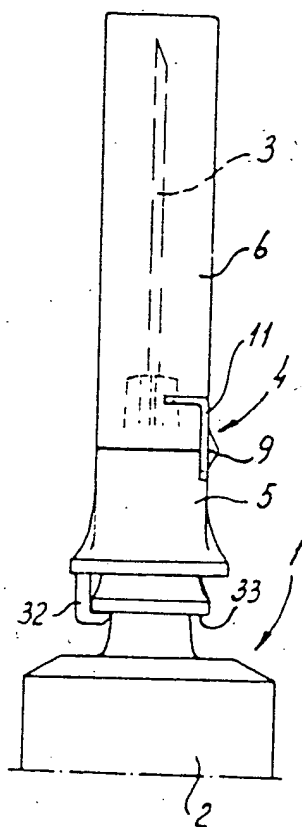


fig-3

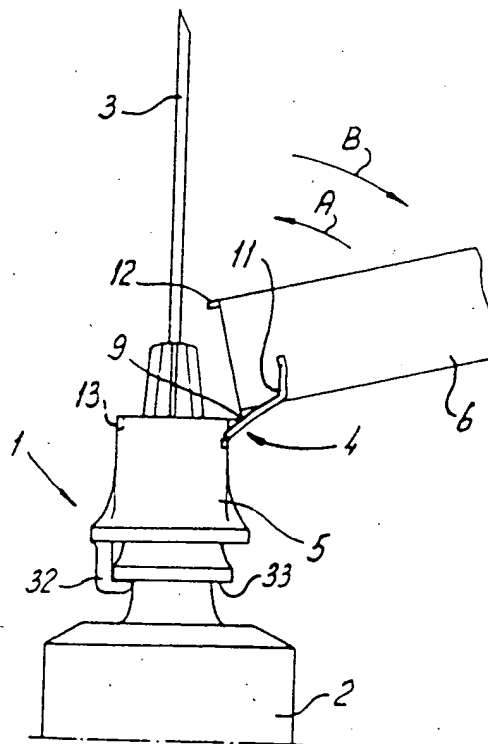
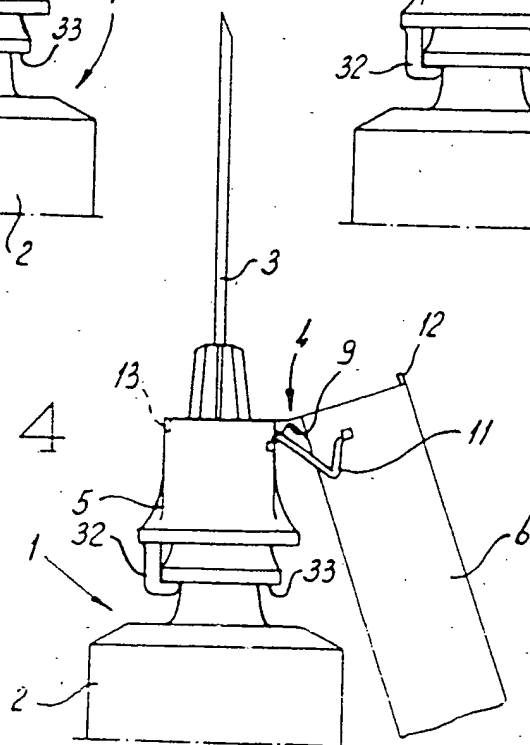


fig-4



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fig-5

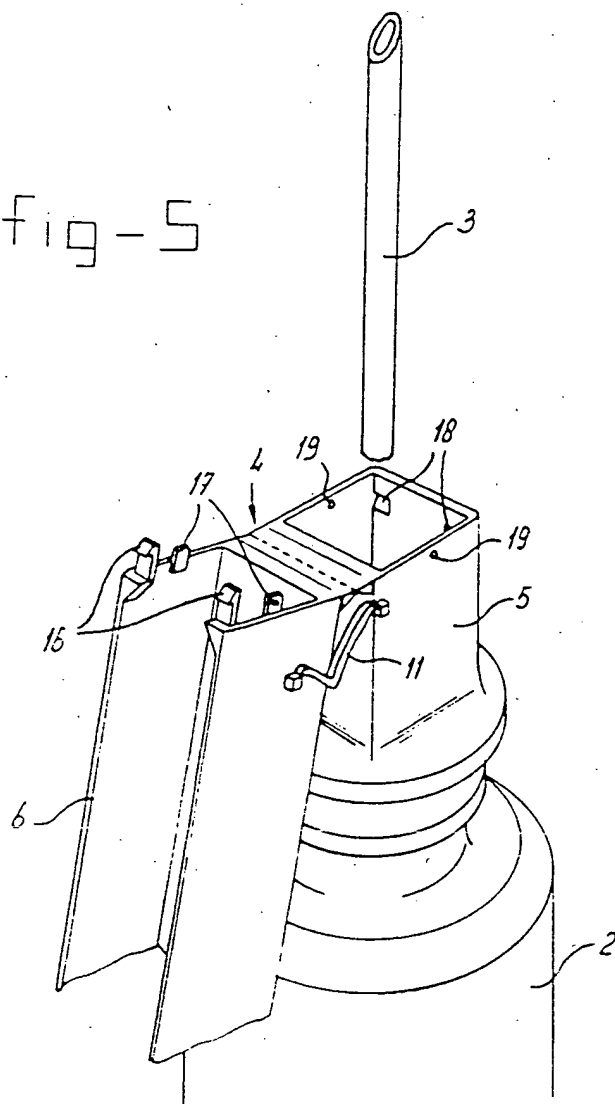


fig-6

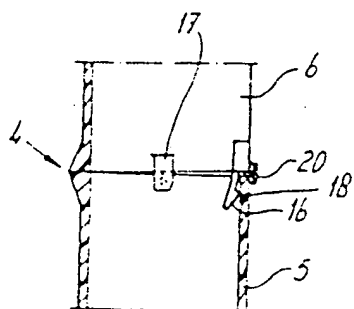
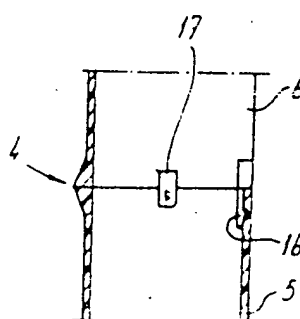

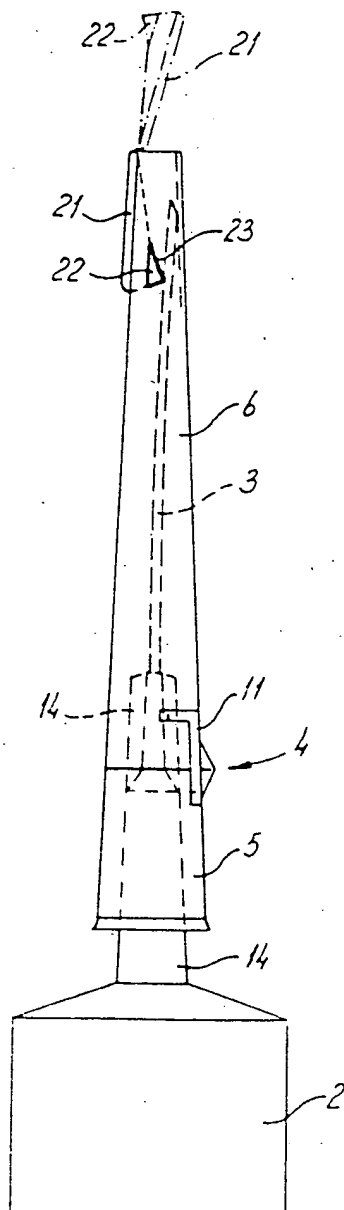


fig-7



4/4

fig - 





III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	FR,A,2 625 103 (WEBER) 30 June 1989 see page 2, line 28 - line 29; figures 3,5 -----	10

ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.

NL 9300043  
SA 71609

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.  
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0489419	10-06-92	AU-A- 8839991	11-06-92
WO-A-9118635	12-12-91	US-A- 5188611	23-02-93
		AU-A- 7994291	31-12-91
		EP-A- 0532612	24-03-93
US-A-4664259	12-05-87	None	
DE-A-3713754	10-11-88	None	
FR-A-2625103	30-06-89	None	